

From the INTERNATIONAL BUREAU

# PCT

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

FLACCUS, Rolf-Dieter  
Bussardweg 10  
50389 Wesseling  
ALLEMAGNE

Eingegangen

02. NOV. 2006

FRIST: .....

Date of mailing (*day/month/year*)  
26 October 2006 (26.10.2006)

Applicant's or agent's file reference  
LTS 2003/009 DE

## IMPORTANT NOTIFICATION

International application No.  
PCT/EP2004/012458

International filing date (*day/month/year*)  
04 November 2004 (04.11.2004)

Applicant

LTS LOHMANN THERAPIE-SYSTEME AG et al

### 1. Transmittal of the translation to the applicant.

☐

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

☒

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

### 2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

None

### 3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Agnes Wittmann-Regis

Facsimile No. +41 22 338 82 70

Facsimile No. +41 22 338 82 70

**TRANSLATION**

**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>LTS 2003/009 DE</b>	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. <b>PCT/EP2004/012458</b>	International filing date (day/month/year) <b>04.11.2004</b>	Priority date (day/month/year) <b>17.11.2003</b>
International Patent Classification (IPC) or national classification and IPC <b>. A61 M37/00 A61 N1/30</b>		
Applicant <b>LTS LOHMANN THERAPIE-SYSTEME AG</b>		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>3</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																										
<p>4. This report contains indications relating to the following items:</p> <table><tr><td><input checked="" type="checkbox"/></td><td>Box No. I</td><td>Basis of the report</td></tr><tr><td><input type="checkbox"/></td><td>Box No. II</td><td>Priority</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td><input type="checkbox"/></td><td>Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VI</td><td>Certain documents cited</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VIII</td><td>Certain observations on the international application</td></tr></table>			<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
<input checked="" type="checkbox"/>	Box No. I	Basis of the report																								
<input type="checkbox"/>	Box No. II	Priority																								
<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																								
<input type="checkbox"/>	Box No. IV	Lack of unity of invention																								
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																								
<input type="checkbox"/>	Box No. VI	Certain documents cited																								
<input type="checkbox"/>	Box No. VII	Certain defects in the international application																								
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																								
Date of submission of the demand		Date of completion of this report																								
Name and mailing address of the IPEA/EP		Authorized officer																								
Facsimile No.		Telephone No.																								

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/012458

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-12 \_\_\_\_\_ as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the claims:
- nos. \_\_\_\_\_ as originally filed/furnished
- nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19
- nos.\* 1-14 \_\_\_\_\_ received by this Authority on 10.08.2005 with letter
- nos.\* \_\_\_\_\_ received by this Authority on of 22.07.2005
- ☒ the drawings:
- sheets 1/2, 2/2 \_\_\_\_\_ as originally filed/furnished
- sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/012458

Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 13, 14

because:

☒ the said international application, or the said claims Nos. 13, 14  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 13-14 relate to subject matter that, in the opinion of the Examining Authority, comes under PCT Rule 67-1(iv). In consequence, no expert opinion has been established in respect of the subject matter of said claims (PCT Article 34(4)(a)(i)).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 13, 14

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished☐ does not comply with the standard

the computer readable form

☐ has not been furnished☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/012458

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

## 1. Statement

Novelty (N)

Claims 1-12

YES

Claims

NO

Inventive step (IS)

Claims 1-12

YES

Claims

NO

Industrial applicability (IA)

Claims 1-12

YES

Claims

NO

## 2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: WO 97/48440 A1 (ALZA CORPORATION)

24 December 1997 (1997-12-24)

D2: US-B1-6 334 856 (ALLEN MARK G ET AL)

1 January 2002 (2002-01-01), cited in the  
application.

Document D1 is considered to be the prior art  
closest to the subject matter of claim 1. Said  
document discloses (the references in brackets are to  
document D1):

a device (2) for the transdermal delivery of active  
substances, said device comprising a backing layer and,  
attached thereto, a reservoir containing an active  
substance, being characterised in that the contact  
surface on the side of the device facing the skin has a  
plurality of microprotrusions ("a plurality of  
microblades 4 (i.e. a blade array)") which are suitable  
for penetrating the skin and which are provided with  
structures ("barbs 50") that make it difficult for  
the protrusions to be withdrawn from the skin (see

/...

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/012458

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

page 7, line 1 to page 15, line 26; page 20, line 27 to page 25, line 7 and figures 2-21, 26 and 27).

The subject matter of claim 1 therefore differs from the known device in that:

said device comprises a number of acicular microprotrusions, the longitudinal contour thereof comprising one or more undercuts.

Thus, the subject matter of claim 1 is novel (PCT Article 33(2)).

Claims 2-12 are dependent on claim 1 and, in consequence, likewise satisfy the requirements of the PCT in respect of novelty and inventive step.

In the light of the documents cited in the international search report, the claimed invention appears to satisfy the requirements of PCT Article 33(1) to (4), that is to say that they appear to be novel, to involve an inventive step and, in addition, to be industrially applicable.